NORTH CAROLINA DIVISION OF AIR QUALITY

Application Review

Issue Date:

Region: Raleigh Regional Office
County: Wake
NC Facility ID: 9200349
Inspector's Name: Dawn Reddix
Date of Last Inspection: 07/25/2019
Compliance Code: 3 / Compliance - inspection

Facility Data

Applicant (Facility's Name): SpecGx LLC - Mallinckrodt Pharmaceuticals

Facility Address:
SpecGx LLC - Mallinckrodt Pharmaceuticals
8801 Capital Boulevard
Raleigh, NC 27616

SIC: 2833 / Medicinals And Botanicals
NAICS: 325411 / Medicinal and Botanical Manufacturing

Facility Classification: Before: Title V **After:** Title V
Fee Classification: Before: Title V **After:** Title V

Permit Applicability (this application only)

SIP: 02D .0503, .0515, .0516, .0521, .1806
NSPS: 02D .0524 (Subparts Dc, VV, NNN, IIII)
NESHAP: 02D .1111 (Subparts EEE, ZZZZ, CCCCCC, JJJJJJ)
PSD: NA
PSD Avoidance: 02Q .0317
NC Toxics: 02D .1100; 02Q .0711
112(r): 02Q .0508(h)
Other: NA

Contact Data

Facility Contact	Authorized Contact	Technical Contact
Timothy Roberts Principal Environmental Engineer (919) 878-2895 8801 Capital Boulevard Raleigh, NC 27616	David Phillips Site Director (919) 878-4733 8801 Capital Boulevard Raleigh, NC 27616	Timothy Roberts Principal Environmental Engineer (919) 878-2895 8801 Capital Boulevard Raleigh, NC 27616

Application Data

Application Number: 9200349.20A
Date Received: 12/27/2019
Application Type: Renewal
Application Schedule: TV-Renewal

Existing Permit Data
Existing Permit Number: 01479/T58
Existing Permit Issue Date: 03/09/2018
Existing Permit Expiration Date: 09/30/2020

Total Actual emissions in TONS/YEAR:

CY	SO2	NOX	VOC	CO	PM10	Total HAP	Largest HAP
2018	14.23	44.56	18.82	28.37	9.43	7.92	3.66 [Aniline]
2017	13.84	42.47	18.56	30.63	10.39	8.61	3.61 [Aniline]
2016	12.19	40.72	17.52	26.01	9.78	7.69	3.55 [Aniline]
2015	14.26	49.19	18.87	30.33	9.84	8.23	3.74 [Aniline]
2014	17.74	51.51	19.29	32.03	9.34	8.69	4.14 [Aniline]

Review Engineer: Eric Crump

Review Engineer's Signature: **Date:**

Comments / Recommendations:
Issue 01479/T59
Permit Issue Date:
Permit Expiration Date:

1. Purpose of Application

SpecGx LLC - Mallinckrodt Pharmaceuticals (SpecGx) is a pharmaceutical plant located in Raleigh, Wake County, North Carolina. The facility operates under Title V Permit No. 01479T58 with an expiration date of June 30, 2020. SpecGx has applied for renewal of their facility's air quality permit. The renewal application was received on December 27, 2019, or at least six months prior to the expiration date. Therefore, the existing permit shall not expire until the renewal permit has been issued or denied. All terms and conditions of the existing permit shall remain in effect until the renewal permit has been issued or denied.

SpecGx has not proposed changes to the existing permit in permit application No. 9200349.20A.

2. Facility Description

SpecGx is a facility that primarily manufactures acetaminophen, an analgesic found in pain and cold medications. This facility currently manufactures most of the U.S. supply of acetaminophen.

Production begins in one of two twin plants, PAP-I (Bldg. 201) or PAP-II (Bldg. 205). First, nitrobenzene is reacted with hydrogen in one of five or six continuous reactors to produce para-aminophenol (PAP). The subsequent processes–distillation, extraction, centrifugation, and condensation—separate the PAP from its by-products, including aniline, K-083 liquid waste (also called tar or aniline tar), and ammonium sulfate. The PAP is crystallized into a powder form and is then reacted with acetic anhydride in one of two acetylator tanks to form acetyl-para-aminophenol (APAP), or acetaminophen. The APAP is purified using extraction, distillation, and filtering processes to separate the APAP from its main by-product, acetic acid, and crystallize the APAP into a powder. The APAP is sold in bulk to facilities that make the final product in tablet or liquid form.

By-products from APAP production are either sold or reused. The K-083 liquid waste is a hazardous waste which is fired in two boilers (ID Nos. BH-2 and BH-7) at the facility. The aniline is sold as a raw chemical by-product, and the ammonium sulfate is sold for use as fertilizer. The acetic acid is either sold as a by-product used in industries such as textile manufacturing or sent back to the acetic anhydride manufacturer to be "recycled" back into acetic anhydride.

SpecGx also has an imaging plant that produces a full line of imaging agents and delivery systems, radiopharmaceuticals, and urology imaging systems for the diagnosis and treatment of disease. The imaging plant includes three small boilers, one generator, and two laboratory hoods that are a potential source of pollution. The manufacturing processes at the imaging plant are not air emission sources.

3. Application Chronology

October 23, 2015	Division of Air Quality issues Permit No. 01479T54 to Mallinckrodt – Raleigh Pharmaceutical Plant (MRPP) as a Title V renewal/modification. In addition to renewing the permit for five years, this action changes the identification number for the K-083 liquid waste storage tank from BH-6 to BH-900, satisfies the requirement under 15A NCAC 2Q .0501(c)(2) to submit a permit application for the K-083 liquid waste storage tank (ID No. BH-900) and Boiler No. 7 (ID No. BH-7) within 12 months of process startup; and incorporates landfill gas/natural gas-fired boiler (ID No. BH-6) into the permit.
October 27, 2015	DAQ notifies MRPP comprehensive performance test results for Boiler No. 2 have been reviewed and accepted, demonstrating compliance with the hazardous waste combustion national emission standards (40 CFR 63 Subpart EEEE). The

	test results were also found acceptable for limiting operating parameters related to specific pollutants not measured by continuous emission monitoring systems.
November 9, 2015	DAQ issues permit applicability determination No. 2725 to MRPP, determining that a 485-horsepower diesel-fired firewater pump is considered an insignificant activity under 15A NCAC 02Q .0503(8) that should be noted in the next permit application.
December 22, 2015	MRRP submits permit application No. 9200349.15C for a minor modification. The permit application did not contain the correct permitting fee and was deemed incomplete.
January 13, 2016	DAQ notifies MRPP comprehensive performance test results for Boiler No. 7 have been reviewed and accepted, demonstrating compliance with some but not all emission limits established under the HWC standards (40 CFR 63 Subpart EEEE).
February 5, 2016	Compliance inspection for Clean Air Act Section 112(r) conducted by Gary Perlmutter, DAQ and Mike Reid, DAQ. Facility appeared to be operating in compliance with all Risk Management Program requirements.
February 26, 2016	MRPP submits remainder of required permitting fee, to DAQ, completing the permit application No. 9200349.15C initially submitted on December 22, 2015 for a minor modification.
April 21, 2016	DAQ issues Permit No. 01479T55 to MRPP for a minor modification including the following: (1) removal of all emission sources associated with the medical imaging plant, (2) reclassification of several emission sources insignificant activities, (3) removal of diesel-fired pump (ID No. IS-WW-6), (4) clarifying applicable requirements under 40 CFR Subpart VV for several emission sources, and (5) making several administrative edits to the permit.
July 7, 2016	DAQ receives air permit application No. 9200349.16A from MRPP. This is the second step of a two-step significant modification under 02Q .0501(c)(2) in which compliance options for boiler BH-7 were changed under MACT Subpart EEE.
August 16, 2016	Compliance inspection conducted by Will Wike, RRO. Facility appeared to be operating in compliance with all permit requirements.
November 7, 2016	DAQ issues Permit No. 01479T56 to MRPP, completing the second step of the two-step significant modification under 15A NCAC 02Q .0501(c)(2) begun with the issuance of Air Quality Permit 01479T53 on July 7, 2015. That permit action changed compliance options for boiler BH-7 under MACT Subpart EEE.
August 15, 2017	Compliance inspection conducted by Will Wike, RRO. Facility appeared to be operating in compliance with all permit requirements.
December 7, 2017	DAQ receives air permit application No. 9200349.17A from MRPP for an ownership change.

January 5, 2018	DAQ issues Permit No. 01479T57 for an ownership change from Mallinckrodt LLC to SpecGX LLC.
February 23, 2018	DAQ acknowledges receipt of air permit application No. 9200349.18A from MRPP for a facility name change.
March 9, 2018	DAQ issues Permit No. 01479T58 for a facility name change from Mallinckrodt - Raleigh Pharmaceutical Plant (MRPP) to SpecGx LLC - Mallinckrodt Pharmaceuticals (SpecGx).
September 26, 2018	Compliance inspection conducted by Steven Carr, RRO. Facility appeared to be operating in compliance with all permit requirements.
December 31, 2018	DAQ notifies MRPP that the EPA Method 9 test results for BH-5 have been reviewed and accepted, demonstrating compliance with the applicable visible emission requirements.
June 5, 2019	Compliance inspection for Clean Air Act Section 112(r) conducted by Matthew Mahler, DAQ, Mike Reid, DAQ, and Elisabeth Nystrom, RRO. Facility appeared to be operating in compliance with all Risk Management Program requirements.
July 25, 2019	Compliance inspection conducted by Dawn Reddix, RRO, with Eric Crump, DAQ. Facility appeared to be operating in compliance with all permit requirements.
December 27, 2019	DAQ receives permit renewal application No. 9200349.19A submitted by SpecGx.
June 3, 2020	SpecGx submits applicability determination request for a 617-horsepower diesel-fired firewater pump (in lieu of the 485-horsepower pump approved in applicability determination No. 2725) to be considered as an insignificant activity under 15A NCAC 02Q .0503(8). This request will be addressed as an amendment to this renewal application.
June 4, 2020	Draft permit and review submitted to RRO and SpecGx for review and comment.
June 15, 2020	Comments on draft permit and review received from RRO.
June 24, 2020	Comments on draft permit and review received from SpecGx.
xxxxx	Public notice published; 30-day public comment period begins.
xxxxx	Region IV of the U.S. Environmental Protection Agency (EPA) notifies DAQ they will (will not) target this permit renewal for review.
xxxxx	Public notice and comment period ends.
xxxxx	EPA 45-day comment period ends.

4. Permit Modifications and Title V Equipment Editor (TVEE) Discussion

The following table summarizes changes to the SpecGx permit resulting from the permit renewal:

Page No.	Section	Description of Changes
Cover and throughout	---	Updated all dates and permit revision numbers
Insignificant Activities List	---	Added 617-horsepower diesel-fired firewater pump (ID No. I-WP-1)
6	2.1 A.2.f.ii 2.1 A.2.f.iii	Changed 40 CFR 50.554(f) to 40 CFR 50.554(g) Changed 40 CFR 50.554(d) to 40 CFR 50.554(e)
7	2.1 B 2.1 B.1.a	Added additional PM limit formulas from 02D .0515 to table Added additional PM limit formulas from 02D .0515
8	2.1 B.1.c, 2.c	Changed "PAP-2" to "PAP-2.1, PAP-2.2"; changed "PAP-7" to "PAP-7.1, PAP-7.2"
11	2.1 D.3 2.1 D.4	Changed "LFG" to "landfill gas" Corrected title of NSPS 40 CFR Part 60, Subpart Dc
13	2.1 D.5.b.iii 2.1 D.5.b.iv 2.1 D.5.b.v 2.1 D.5.b.vi 2.1 D.5.c.vi 2.1 D.5.e	Added "dry basis" to description of carbon monoxide limit Added "dry basis" to description of hydrocarbons limit Added "combined" to description of hydrogen chloride and chlorine limit Corrected spelling of "lieu" Added "combined" to description of hydrogen chloride and chlorine limit Changed 40 CFR 63. 1206(d) to 40 CFR 63. 1217(d)
15	2.1 D.5.l.ii	Spelled out the acronym "CMS" (continuous monitoring system)
22	2.1 D.5.qq	Added 40 CFR 63.10(c) to list of CFR citations at the end
25	2.2 A.1.c.iv	Inserted "(K-083 liquid waste) between the words "tar" and "fired"
28	2.2 A.2.b.i 2.2 A.2.b.ii	Replaced "APAP" with "acetyl-para-aminophenol (APAP)" Inserted "(aniline tar)" between the words "waste" and "in"
30	2.3 A.1.b, c	Changed the due date for submittal of RMP update and revision
31-40	3	Updated General Conditions to Version 5.3 dated August 21, 2018

The following change was made to the Title V Equipment Editor: the addition of Source ID No. I-WP-1, 617-horsepower diesel-fired firewater pump [GACT ZZZZ].

5. Description of Changes and Estimated Emissions

When the Spec Gx permit was last renewed on October 23, 2015, a modification included with the renewal made the following changes to the facility:

- Added a landfill gas-fired/natural gas-fired boiler (ID No. BH-6), with a heat input of 34 million Btu per hour.
- Removed a natural gas-fired boiler equipped with a low-NOx burner (ID No. BH-3). The boiler has been removed from service since 2012.

As discussed in the review for Permit No. 01479T54 (B. Gatano, 10/23/15), this modification resulted in a net decrease in potential emissions of SO_2 (from 263 tons/yr to100) and NOx (from 205 tons/yr to 100). While an increase in emissions of acetaldehyde, acrolein, ammonia, benzene, benzo(a)pyrene, formaldehyde, n-hexane, and toluene was expected with the addition of boiler BH-6 to the site, only benzene and ammonia were found to exceed their Toxic Air Pollutant Permitting Emissions Rates (TPERs). Further analysis indicated there would be no unacceptable risk to human health from the small increase in emissions of benzene and ammonia.

A minor modification in Permit No. 01479T55 included the following:

- removal of all emission sources associated with the medical imaging plant
- reclassification of several emission sources insignificant activities
- removal of diesel-fired pump (ID No. IS-WW-6)
- clarifying applicable requirements under 40 CFR Subpart VV for several emission sources, and
- several administrative edits to the permit.

As discussed in the review for Permit No. 01479T55 (B. Gatano, 4/21/16), this modification resulted in a net decrease in potential emissions of SO_2 and NOx to less than 100 tons/yr, respectively.

On November 9, 2015, DAQ issued permit applicability determination No. 2725 to the SpecGx facility. The determination stated that a 485-horsepower diesel-fired firewater pump added to the facility would be considered an insignificant activity under 15A NCAC 02Q .0503(8) because:

- its emissions would not violate any applicable emissions standard,
- its potential uncontrolled criteria pollutant emissions would be less than five tons per year, and
- its potential uncontrolled HAP emissions are below 1000 pounds per year.

Because the used 485-horsepower pump did not work, SpecGx purchased a 617-horsepower diesel-fired firewater pump (ID No. I-WP-1). On June 3, 2020, SpecGx submitted a new applicability determination request for the larger pump, effectively updating Applicability Determination No. 2725. While the increased size of the firewater pump would mean an increase in emissions, the uncontrolled criteria pollutant emissions would still be less than five tons per year, and the uncontrolled HAP emissions would still be below 1000 pounds per year. Therefore, the firewater pump would still be considered an insignificant activity.

The firewater pump is subject to 40 CFR Part 63, Subpart ZZZZ, and according to §63.6590(c)(1) of this subpart, must meet the requirements of this rule by meeting the requirements of 40 CFR part 60 subpart IIII. Because the pump is an insignificant activity, it will be added to the permit, but will not be subject to any permit conditions. Continued compliance is expected.

6. Regulatory Review

No state regulations will be added, removed, or changed in this permit as a result of this application. The permit has been updated to reflect the most current stipulations for all applicable regulations.

The SpecGx facility is subject to the following state regulations:

A . *02D .0503: Particulates from Fuel Burning Indirect Heat Exchangers*. The four boilers at the facility are subject to this regulation. Allowable particulate matter (PM) emission limit are determined from the equation $E = 1.090(Q)^{-0.2594}$, where:

E= allowable emission limit for PM in pounds per million Btu

Q = maximum heat input in million Btu per hour.

The following table shows the allowable PM emission limit for these boilers, along with the estimated emissions, based on emission factors from the permit review for Permit No. 01479T54 (B. Gatano, 10/23/2015).

ID No.	Description	Maximum heat input, million Btu per hour	Allowable emissions, pounds per million Btu (see note)
BH-2	Natural gas/K-083 liquid waste fired boiler equipped with low-NOx burner	30.6	0.33
BH-5	Natural gas/No. 2 fuel oil/landfill gas-fired boiler equipped with low-NOx burner	96.2	0.28
BH-6	Natural gas/landfill gas-fired boiler	34	0.26
BH-7	Natural gas/landfill gas/K-083 liquid waste-fired boiler equipped with low-NOx burners	66	0.25
Note: The limit for any given boiler was established based on the maximum heat input of all active boilers at the facility at the time the boiler was installed. While several boilers have been removed from the facility since the current boilers were added, as stated under 02D .0503(e), "the removal of a fuel burning indirect heat exchanger shall not change the allowable emission limit of any fuel burning indirect heat exchanger whose allowable emission limit has previously been established."			

Based on emission factors for each of the fuels burned in the boilers, the maximum PM emissions expected from the boilers are provided as follows:

- No. 2 fuel oil – 0.024 pounds per million Btu (based on an emission factor of 3.3 pounds per 10^3 gallons and a fuel heating value of 140,000 Btu/gallon.[1])
- Natural gas – 0.007 pounds per million Btu (as provided in the DAQ spreadsheet.[2])
- Landfill gas – 0.0082 pounds per million Btu (based on an emission factor of 8.2 pounds per million cubic feet of methane, a methane content of landfill gas of 52.6, and a Btu value of landfill gas of 520 Btu per standard cubic feet.[3])
- K-083 liquid waste – 0.021 pounds per million Btu (based on an emission factor of 0.30 pounds of PM per 1000 pounds of feed[7] and heating content of waste of 14,000 Btu per pound.[4])

As shown from these emission factors, expected PM emissions are well below the emission limits. No changes to the permit are required under this renewal. Continued compliance is expected.

B. *02D .0515: Particulates from Miscellaneous Industrial Processes*: The dryers, sizing, packaging, and housekeeping equipment (PAP & APAP Processes) listed below are subject to this rule.

- Two (2) PAP vacuum dryers (ID Nos. PAP-2.1, PAP-2.2)
- Two (2) PAP vacuum dryers (ID Nos. PAP-7.1, PAP-7.2)
- Pneumatic conveyor and bulk bagging packaging station (ID No. PAP-8)
- Eight (8) APAP packaging stations and three (3) vacuum dryer drop hoppers (ID No. APAP-

[1] Emission factor for No. 2 fuel oil is from the DAQ's "Fuel Oil Combustion Emission Calculator Revision E" (02/01/2010).
[2] Natural gas emission factor is from the DAQ's "Natural Gas Combustion Emission Calculator Revision K" (06/19/2012).
[3] Properties of landfill gas as reported in Air Permit Application 9200349.14C.
[4] Permit review for Air Permit No. 01479T46 (Fern Paterson, 3/17/2010).

2.1, APAP-2.2
- APAP House Vacuum System (ID No. APAP-3)
- Sizing equipment associated with #2 Dryer/Drop Hopper with pneumatic solids conveying system (ID Nos. APAP-8)
- Sizing equipment associated with #4 Dryer/Drop Hopper (ID No. APAP-10)
- Sizing equipment associated with #3 Dryer/Drop Hopper (ID No. APAP-11)
- Sizing equipment associated with #2 Dryer/Drop Hopper (ID No. APAP-12)
- C&M bulk bagging operations with pneumatic conveyor system (ID No. APAP-17)
- Bulk bagging operations with pneumatic conveyor system (ID No. APAP-18)
- PAP Charging pneumatic conveyor and product receivers (ID No. APAP-21)

PM emissions from all of the above listed equipment is controlled with fabric filters—either with pneumatic conveyor systems (APAP-8, APAP-17, APAP-18, and APAP 21), or broken bag detectors (APAP-2, APAP-3, APAP-10, APAP-11, APAP-12; PAP 2, PAP-7, and PAP-8). Based on the sizes of these control devices, it has been determined that the PM emissions from the sources are very limited. The controls themselves are not actually necessary for compliance with the standard; rather they exist primarily for conservation of product. For this reason, no monitoring, recordkeeping, or reporting requirements were included in the permit. No changes to the permit are required under this permit renewal. Continued compliance is expected.

C. *02D .0516: Sulfur Dioxide Emissions from Combustion Sources*. The four boilers onsite (BH-2, BH-5, BH-7, and BH-8) are subject to this state regulation, which limits sulfur dioxide (SO_2) emissions to 2.3 pounds per million Btu heat input. Because of the inherently low sulfur content of natural gas, landfill gas, No. 2 fuel oil, and K-083 liquid waste, no monitoring, recordkeeping, or reporting is required to demonstrate compliance of these boilers with this standard when firing these fuels. Continued compliance is expected.

D. *02D .0521: Control of Visible Emissions*. This rule applies to all fuel burning sources and other processes that may have visible emissions, unless other state rules with emission standards apply. Sources included are:
- Boilers BH-2, BH-5, BH-7, and BH-8
- Two (2) PAP vacuum dryers (ID Nos. PAP-2.1, PAP-2.2)
- Two (2) PAP vacuum dryers (ID Nos. PAP-7.1, PAP-7.2)
- Pneumatic conveyor and bulk bagging packaging station (ID No. PAP-8)
- Eight (8) APAP packaging stations and three (3) vacuum dryer drop hoppers (ID No. APAP-2.1, APAP-2.2)
- APAP House Vacuum System (ID No. APAP-3)
- Sizing equipment associated with #2 Dryer/Drop Hopper with pneumatic solids conveying system (ID Nos. APAP-8)
- Sizing equipment associated with #4 Dryer/Drop Hopper (ID No. APAP-10)
- Sizing equipment associated with #3 Dryer/Drop Hopper (ID No. APAP-11)
- Sizing equipment associated with #2 Dryer/Drop Hopper (ID No. APAP-12)
- C&M bulk bagging operations with pneumatic conveyor system (ID No. APAP-17)
- Bulk bagging operations with pneumatic conveyor system (ID No. APAP-18)
- PAP Charging pneumatic conveyor and product receivers (ID No. APAP-21)
- 100 kW standby diesel generator serving the wastewater treatment plant (WW-1), classified as an insignificant activity

As sources manufactured after July 1, 1971, they are subject to the 20% opacity limitation in the rule.

The pneumatic conveyor systems **(ID Nos. APAP-8, APAP-17, APAP-18, and APAP-21)** and sources equipped with broken bag detectors **(ID Nos. APAP-2, APAP-3, APAP-10, APAP-11,**

APAP-12, PAP-2, PAP-7 and PAP-8) do not require monitoring, recordkeeping, or reporting to demonstrate compliance with this visible emission standard. Similar to the discussion above with regard to the particulate standard 02D .0515, visible emissions from the sources are very limited. The controls themselves are not so much necessary for compliance as for conservation of product. For this reason, no monitoring, recordkeeping, or reporting requirements were included in the permit.

Boilers BH-2, BH-6 and BH-7 are subject to the visibility requirements in 02D .0521. Boiler BH-5 is subject to 02D .0521 when firing natural gas, and to 40 CFR 60 Subpart Dc when firing No. 2 fuel oil. As visible emissions are not expected from these boilers, monitoring, recordkeeping, or reporting is not required to demonstrate compliance with this standard.

Emergency diesel generator WW-1 is classified as an insignificant activity as defined in 15A NCAC 02Q .0503(8). As such, no monitoring, recordkeeping, or reporting is required for this source.

Continued compliance with visibility requirements is expected for these sources.

E. *02D .1806: Control and Prohibition of Odorous Emissions*. This regulation is applicable facility-wide and is state-enforceable only. SpecGx is required to implement management practices or install and operating odor control equipment as needed to prevent emissions from causing or contributing to objectionable odors beyond the facility's boundary. Continued compliance is expected.

No state regulations will be added, removed, or changed in this permit as a result of this application. The permit has been updated to reflect the most current stipulations for all applicable regulations.

7. National Emission Standards for Hazardous Air Pollutants (NESHAPs): Maximum and/or Generally Achievable Control Technology (MACT/GACT)

The status of the SpecGx facility with regard to NESHAPs has not changed since the last permit renewal was issued. Since that time, this facility has not become subject to any additional NESHAPs, nor have the requirements for the facility under the existing NESHAPs changed.

The facility is subject to the following NESHAPs:

A. *National Emission Standards for Hazardous Air Pollutants from Hazardous Waste Combustors, 40 CFR Part 63 Subpart EEE*. Boilers BH-2 and BH-7 are permitted to fire K-083 liquid waste, an aniline tar liquid waste generated by the PAP manufacturing process. Since K-083 liquid waste meets the definition of hazardous waste, both boilers are subject to 40 CFR Part 63 Subpart EEE. While SpecGx is an area source of hazardous air pollutants (HAPs), it is required to obtain a Title V permit under 40 CFR 63.1200(a)(2).

The requirements under Subpart EEE are extensive. The facility must meet emission limits for numerous pollutants, develop and implement a feed stream analysis plan, conduct initial and periodic comprehensive performance testing, meet operating limits, ensure operator testing and certification, and meet other monitoring, recordkeeping, and reporting requirements. A detailed summary of the requirements is provided in the last permit renewal review for Permit No. 01479T54 (B. Gatano, 10/23/2015). This permit renewal does not affect the requirements for these sources under Subpart EEE. Continued compliance is expected.

B. *National Emission Standards for Hazardous Air Pollutants for Industrial, Commercial, and Institutional Boilers at Area Sources, 40 CFR Part 63, Subpart JJJJJJ (6J)*. Boiler BH-5 is subject to this NESHAP. Having been constructed before June 4, 2010, it is considered an existing boiler under this rule. Subpart 6J subjects this boiler to work practice standards, including an initial tune up

(completed March 14, 2012), tune-ups every 24 months, and a one-time energy assessment (completed March 21, 2014). This permit renewal does not affect the requirements for these sources under Subpart 6J. Continued compliance is expected.

It should be noted that Boilers BH-2 and BH-7 are not subject to Subpart 6J, since as specified in 40 CFR 63.11195(c), any boiler subject to 40 CFR 62 Subpart EEE is not subject to Subpart 6J.

C. *National Emission Standards for Hazardous Air Pollutants for Source Category: Gasoline Dispensing Facilities, 40 CFR Subpart CCCCCC (6C).* A 500-gallon gasoline storage tank (ID No. I-GDF-1) is subject to this GACT standard. This tank has been classified as an insignificant activity under 15A NCAC 02Q .0503(8) because its emissions would not violate any applicable emissions standard, its potential uncontrolled criteria pollutant emissions are no more than five tons per year and its potential uncontrolled HAP emissions are below 1000 pounds per year. For this reason, gasoline storage tank I-GDF-1 is not subject to any permit conditions. Continued compliance is expected.

D. *National Emissions Standards for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines, 40 CFR Subpart ZZZZ.* A 100 kW standby diesel generator serving the waste water treatment plant (ID No. I-WW-1) is subject to this GACT standard. This generator has been classified as an insignificant activity under 15A NCAC 02Q .0503(8) because its emissions would not violate any applicable emissions standard, its potential uncontrolled criteria pollutant emissions are no more than five tons per year and its potential uncontrolled HAP emissions are below 1000 pounds per year. For this reason, generator I-WW-1 is not subject to any permit conditions. Continued compliance is expected.

As explained earlier in Section 5, the firewater pump (ID No. I-WP-1) being added to the permit is also subject to Subpart ZZZZ. It is also classified as an insignificant activity, and will not be subject to any permit conditions. Continued compliance is expected.

8. New Source Performance Standards (NSPS)

The following NSPS apply to the SpecGx facility:

A. *Standards of Performance for Small Industrial-Commercial-Institutional Steam Generating Units, 40 CFR Part 60, Subpart Dc*. Boilers BH-5, BH-6, and BH-7 are subject to this rule, as they were constructed, modified, or reconstructed after June 9, 1989 and have a maximum design heat input capacity greater than 10 million Btu per hour and less than 100 million Btu per hour. Boiler BH-5, which fires No. 2 fuel oil, is subject to the SO_2 and visible emission standards of this rule (sulfur content of any fuel oil shall not exceed 0.5 percent by weight, visible emissions more than 20 percent opacity when averaged over a six-minute period, except for one six-minute period per hour of not more than 27 percent opacity, and recordkeeping and Method 9 visible emission observation requirements). The facility must record monthly fuel usage for all three boilers as required under NSPS Subpart Dc. No other requirements apply under NSPS Subpart Dc when firing natural gas. No changes to the permit condition are required under this permit renewal. Continued compliance is expected.

B. *Standards of Performance for Equipment Leaks of VOC in the Synthetic Organic Chemicals Manufacturing Industry for which Construction, Reconstruction, or Modification Commenced After January 5, 1981, and on or Before November 7, 2006, 40 CFR Part 60, Subpart VV*. SpecGx is required to check equipment in heavy liquid service (associated with PAP-18, 19, and 20) monthly for leaks with visual, audible or olfactory methods. Any leaks detected must be repaired within 15 business days, with some specific exceptions. Finally, the facility must comply with

recordkeeping and reporting requirements under NSPS Subpart VV. No changes to the permit condition are required under this permit renewal. Continued compliance is expected.

C. *Standards of Performance for VOC Emissions from SOCMI Distillation Operations, 40 CFR Part 60, Subpart NNN*. The acetic acid evaporator in the acetaminophen production process (ID No. APAP-1) and distillation units in the PAP production operations included in the "Confidential Building 205 Equipment List" (ID No. PAP-22) are subject to this regulation. SpecGx demonstrates compliance with this subpart by maintaining a total resource effectiveness (TRE) index value that is (a) greater than 8.0 for each of the affected sources; and (b) greater than 1.0 for each of the affected sources without use of VOC emission control devices, in accordance with 40 CFR 60.662(c). The facility must also recalculate the TRE index when process changes are made and follow recordkeeping and reporting as required by NSPS Subpart NNN. No changes are required under this permit renewal/modification, and continued compliance is anticipated.

D. *Standards of Performance for Stationary Compression Ignition Internal Combustion Engines, 40 CFR Part 60, Subpart IIII*. As explained earlier in Section 5, the firewater pump (ID No. I-WP-1) being added to the permit is subject to this rule. It is also classified as an insignificant activity, and will not be subject to any permit conditions. Continued compliance is expected.

9. New Source Review (NSR)/Prevention of Significant Deterioration (PSD)

SpecGx is in Wake County, which is in attainment or unclassified for all PSD regulated pollutants. Being a chemical processing plant, it belongs to one of the 28 listed source categories with major source thresholds of 100 tons per consecutive 12-month period for each criteria pollutant, under 40 CFR 51.166 (b)(1)(i)(a). SpecGx has accepted avoidance conditions in their permit which limit total sulfur dioxide (SO_2) and total nitrogen oxide (NOx) emissions to less than 100 tons each per consecutive 12-month period. This permit renewal does not affect this status. Continued compliance is expected.

10. Risk Management Program (Clean Air Act, Section 112(r))

40 CFR Part 68 requires stationary sources storing more than threshold quantities of regulated substances to develop a risk management plan (RMP), in accordance with Section 112(r) of the Clean Air Act. The RMP lists potential effects of a chemical accident, steps the facility is taking to prevent an accident, and emergency response procedures to be followed if an accident occurs.

The U.S. EPA received the facility's current RMP submittal on January 31, 2019; its anniversary date is on January 31, 2024. The facility's EPA ID No. is 1000 0010 6235. Currently, the only regulated substance at the facility is anhydrous ammonia. The maximum intended quantity for anhydrous ammonia storage is 285,090 pounds; the threshold amount is 10,000 pounds. Liquid hydrogen storage was previously delisted as the quantity stored onsite is 9,200 pounds, which is below the 10,000-pound threshold amount.

The SpecGx facility was last inspected for compliance with their RMP on June 5, 2019 and appeared to be in compliance with Section 112(r). As this is a "high risk" facility, it is recommended that it be inspected every 2.5 years. Continued compliance is expected.

10. Compliance Assured Monitoring (CAM)

40 CFR Part 64 requires development of a continuous CAM plan for a pollutant specific unit if that unit:

- is located at a major source required to obtain a 40 CFR Part 70 or Part 71 permit;
- is subject to an emission limitation or standard for a regulated air pollutant;
- uses an active control device to comply with that emission limitation or standard; and
- has potential pre-control potential emission rate exceeding the major source threshold (100 tons/year for criteria pollutants, 10 tons/year of a single HAP, or 25 tons/year of multiple HAPs.

CAM is not applicable to the SpecGx facility because it is not a major source. The facility is an area source of HAPs and criteria pollutants; it is required to obtain a Title V permit pursuant to 40 CFR 63.1200(a)(2) only because it is subject to MACT Subpart EEE. This permit renewal with consolidated minor modification does not affect the facility's status with respect to CAM.

11. Facility-wide Toxics Review

The SpecGx facility is subject to emission limits for acetic acid, ammonia, aniline, arsenic and inorganic arsenic compounds, benzene, chlorine, and nitrobenzene in accordance with 15A NCAC 02D .1100, "Control of Toxic Air Pollutants". These emission limits were established as a facility-wide worst-case single stack modeling demonstration. To ensure compliance with these limits, the permit establishes limits for production of APAP, and for the rate at which K-083 liquid waste may be burned. In addition, the permit allows the K-083 liquid waste storage tank (BH-900) to be filled only during specific hours when the tank is vented directly to the atmosphere. Annual inspections of the condenser system (ID No. COND-2 and COND-3), and periodic inspections and maintenance of the packed bed scrubber (ID No. PAPSCRUB) are required, along with appropriate recordkeeping and reporting for these requirements. This permit renewal does not affect this status. Continued compliance is expected.

The permit lists the following NC toxic air pollutants (TAPs) and their respective toxic permit emission rates (TPERs) as established in 15A NCAC 02Q .0711, "Emission Rates Requiring a Permit": benzo(a)pyrene, cadmium metal (elemental unreacted), carbon disulfide, formaldehyde, manganese and compounds, n-hexane, mercury vapor, methylene chloride, nickel metal, polychlorinated biphenyls, and toluene. SpecGx has demonstrated that its facility-wide actual emissions do not exceed the TPERs. The permit requires SpecGx to obtain a permit if actual emissions from all sources at the facility should exceed the TPERs; and to maintain records that demonstrate compliance with each TPER. Based on the most recent inspection, SpecGx has been complying with this requirement. Continued compliance will be determined during subsequent inspections.

12. Facility Emissions Review

There is no change in Title V potential emissions under this permit renewal. The table on the header page of this review lists reported emissions of criteria pollutants and HAPs for SpecGx for the years 2014 through 2018 after application of required emission controls. They show emissions of criteria pollutants well below the 100 ton per year PSD threshold. Aniline is the largest single HAP emitted from the facility.

13. Compliance Status

The SpecGx facility was most recently inspected on July 25, 2019 by Dawn Reddix of the Raleigh Regional Office. The company appeared to be in compliance with all applicable requirements at that time.

14. Public Notice/EPA and Affected State(s) Review

A notice of the DRAFT Title V Permit shall be made pursuant to 15A NCAC 02Q .0521. The notice will provide for a 30-day comment period, with an opportunity for a public hearing. Consistent with 15A

NCAC 02Q .0525, the EPA will have a concurrent 45-day review period. Copies of the public notice shall be sent to persons on the Title V mailing list and EPA. Pursuant to 15A NCAC 02Q .0522, a copy of each permit application, each proposed permit and each final permit shall be provided to EPA. Also, pursuant to 02Q .0522, a notice of the DRAFT Title V Permit shall be provided to each affected State at or before the time notice is provided to the public under 02Q .0521 above. Virginia is an affected state within 50 miles of the facility; there are no affected states or local programs within 50 miles of the facility.

15. Other Regulatory Considerations

None of the following were required for Permit Application No. 9200349.20A:

- a Professional Engineer's seal,
- a zoning consistency determination, or
- a permit fee.

16. Recommendations

DAQ has reviewed the permit application for SpecGx LLC - Mallinckrodt Pharmaceuticals located in Raleigh, Wake County to determine compliance with all procedures and requirements. DAQ has determined that this facility is complying or will achieve compliance, as specified in the permit, with all requirements that are applicable to the affected sources. DAQ recommends the issuance of Air Permit No. 01479T59.